



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Nonpharmacologic Treatment for Maternal Mental Health Conditions

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Nonpharmacologic Treatment for Maternal Mental Health Conditions*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT:

Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Nonpharmacologic Treatment for Maternal Mental Health Conditions*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Nonpharmacologic Treatment for Maternal Mental Health Conditions, including those

that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/mental-health-pregnant/protocol>

This is to notify the public that the EPC Program would find the following information on

Nonpharmacologic Treatment for Maternal Mental Health Conditions helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential;

marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What are the effectiveness and comparative effectiveness and harms of nonpharmacologic treatments for mental health conditions in perinatal individuals?

- a) Depressive disorders
- b) Bipolar disorder
- c) Anxiety disorders
- d) Post-traumatic stress disorder
- e) Obsessive-compulsive disorder

KQ 2: What are the comparative effectiveness and harms of nonpharmacologic treatments compared with pharmacologic treatment alone for mental health conditions in perinatal individuals?

- a) Depressive disorders
- b) Bipolar disorder
- c) Anxiety disorders
- d) Post-traumatic stress disorder
- e) Obsessive-compulsive disorder

Population(s)

- Perinatal individuals
 - Individuals who are pregnant or postpartum (up to 12 months after delivery) with new or preexisting diagnosis of depression disorder, bipolar disorder, anxiety disorders, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD)
 - Diagnoses must be confirmed via clinical interview or validated screening tool (e.g., Edinburgh Postnatal Depression Scale [EPDS]; Patient Health Questionnaire-9 [PHQ-9]) with a commonly accepted threshold
 - EXCLUDE: studies that evaluate patients with depressive or anxiety symptoms in contrast with diagnoses of depression or anxiety, including studies that include patients with screening tool values below a threshold consistent with diagnosis
 - EXCLUDE: populations in which the primary condition is phobia of pregnancy (i.e., tokophobia)
 - EXCLUDE: studies with mixed populations (e.g., perinatal and non-perinatal, mental health condition and non-mental health condition), unless $\geq 90\%$ of the studied population represent an eligible population for the review. This exclusion criterion does not apply to populations with multiple eligible mental health conditions; studies of perinatal individuals with two or more conditions (e.g., studies targeting individuals with both depression and anxiety) will be included.
 - EXCLUDE: Studies of patients with substance use disorders, exclusively.

Intervention

- **Nonpharmacologic modalities**

To be included, studies must evaluate one or more nonpharmacological modalities such as those listed below. Although the list sought to be comprehensive, it is not intended to be restrictive to modalities not appearing on the list. If a study otherwise meets eligibility criteria and describes a nonpharmacological intervention involving a form of psychotherapy or complementary/alternative therapy (aside from those specified for exclusion) it will be considered for inclusion.

Note that the list of modalities includes treatments for any of the mental health conditions under consideration, recognizing that not all therapies are appropriate for all conditions.

Psychotherapies

- Cognitive behavior therapy (CBT)
 - Examples: trauma-focused CBT, mindfulness-based, cognitive processing therapy, cognitive restructuring, cognitive remediation therapy, stress inoculation training
- Acceptance and commitment therapy (ACT)
- Psychodynamic therapy
- Interpersonal psychotherapy (IPT)
- Supportive therapy
- Dialectical behavioral therapy (DBT)
- Exposure therapy
 - Example: Narrative Exposure Therapy (NET), prolonged exposure therapy

- Eye movement desensitization and reprocessing therapy
- Imagery rehearsal therapy
- Social rhythm therapy

Psychoeducation

- Trauma affect regulation
- Problem solving

Other

- Electroconvulsive therapy (ECT)

Complementary/alternative therapies

- Mindfulness
- Exercise
- Relaxation
- Yoga
- Tai Chi
- Self-hypnosis and relaxation
- Acupuncture
- Bright light therapy
- Sleep therapy
- Writing, art, music therapy
- EXCLUDE: studies with interventions that are poorly specified or not structured programs (i.e., cannot be reasonably replicated in practice or future research)
- EXCLUDE: unsupervised peer-to-peer or social media interventions
- EXCLUDE: interventions delivered through ingestion or parenterally, and surgical or invasive interventions (with the exception of acupuncture or ECT) (e.g., omega-3 fatty acid, St. John's wort, kava, valerian, theanine)
- EXCLUDE: interventions designed to address issues other than the mental health conditions of interest (e.g., diet changes, weight loss, lactation training, reintroduction of sexual activity)
- EXCLUDE: interventions focused on the processes of delivering of care (e.g., collaborative care model)

Mechanisms of delivery

The above intervention modalities may be delivered in diverse ways in different settings, by different personnel, with different intensities. We will include studies of the above that directly compare different mechanisms of delivery below. We have purposefully separated the content of modalities of interest from means by which they may be delivered since mechanisms of delivery (e.g., telehealth) are not interventions in their own right.

Number of participants

- Individuals
- Group

Type of participants

- Individual
- Couple
- Family

Type of provider

- Professional (e.g., psychotherapist, exercise instructor)
- Community based non-professional or peer
- Not applicable (i.e., self-administered)

Type of modality

- In-person
- Online via computer
- Online via mobile app

Duration

- 'Brief', 'short-term'
- 'Prolonged'
- *N.B. many studies use diverse labels to signify the duration of the intervention delivered. The meaning of these labels will be extracted as part of our intervention extraction process. We will not exclude studies based on their duration.*

Outcomes

Outcomes in bold font, with footnote "a" will be prioritized (i.e., will be included in Evidence Profiles)

- **Scores on psychological assessments¹** (for each evaluated condition)
 - Including self-assessed symptoms of mental health condition^b
- **Cure/resolution of symptoms or condition^a**
- **Parent-infant bonding^{a,2}**
- **Suicide^{a,b}**
 - **Suicidal thoughts^a**
 - **Attempted suicide^a**
 - **Death by suicide^a**
- **Thoughts of harming the baby, including thoughts of extended suicide^{a,b}**
- **Adherence to mental health treatment^{a,b}**
- Satisfaction with intervention^b
- Perceived self-efficacy for parenthood
- Perceived self-efficacy for management of mental health
- Harms of treatment
- Quality of life
- Return to work
- Maternal clinical outcomes (e.g., preeclampsia, preterm delivery)
- Safe family environment
- Fetal/neonatal/pediatric clinical outcomes
 - Live birth
 - Infant feeding success
 - Infant growth
 - Pediatric death
 - Pediatric development (e.g., neurodevelopmental milestones)
 - Pediatric cognitive and academic achievement
 - Pediatric social/emotional wellbeing
- Prenatal care utilization. E.g., completion of prenatal visits, completion of recommended prenatal services, unexpected health care utilization (e.g., emergency department/triage visits), postpartum care follow-up

^a Prioritized outcome

^b From perinatal depression core outcome set (recommended 9 core outcomes) Helberg et al. 2021. PMID 34047454

Potential Modifiers

- Pregnancy status (pregnant, postpartum after live birth, postpartum after fetal loss or infant death or needing intensive care, breastfeeding; change of status within study period)
- Severity of mental health conditions (e.g., mild, moderate or severe depression; depression with or without anxiety, psychosis)
- Comorbidities, including other mental health conditions
- Age
- Race/ethnicity
- Religion/faith
- Birthplace (e.g., immigrant from Latin America vs. U.S.-born)
- Gender identification
- Sexual orientation
- Socioeconomic factors
- Geographic region, urbanicity
- Patient-provider congruence (e.g., with respect to racial, ethnic, language, and other socioeconomic factors)
- Use of social media
- Partner support
- Interpersonal violence (including partner violence)
- Availability of family leave, paid or unpaid
- Drug use
- History of abortion
- History of pregnancy loss
- Intended pregnancy
- Parity
- Insurance status
- Accessibility issues (e.g., internet access, in particular for telehealth interventions)
- COVID-19 pandemic (as defined by study authors)

Setting

- Ambulatory with exception of individuals in hospital due to non-mental health pregnancy or postpartum complications (i.e., exclude patients in acute inpatient psychiatric setting)
- Treatment delivery method (all including in-person, telehealth, digital)
- High-income countries (as defined by World Bank as of May 11, 2023)

Design

- Randomized controlled trials
- EXCLUDE: Nonrandomized comparative studies
- EXCLUDE: Single group (noncomparative) studies, including case reports or series
- EXCLUDE: Studies with N<10 per arm
- EXCLUDE: Studies published only in dissertation or conference abstract format

We will collect SRs to identify potentially eligible primary studies (within date restrictions) and possibly to narratively summarize older studies of earlier foundational nonpharmacological interventions.

For topics with robust existing SRs (e.g., non-pharmacological interventions for perinatal depression), we will consider (with partners and our task order officer

[TOO]) updating these SRs (relying on the published SRs for all data pertaining to the older primary studies)

Eligibility criteria specific to Key Question 1 (nonpharmacologic vs. nothing/treatment as usual/usual care or vs. other nonpharmacologic)

Intervention

- May include same pharmacologic co-intervention as comparator group

Comparators

- No nonpharmacologic treatment
- Other nonpharmacologic modality
- May include same pharmacologic co-intervention as intervention group

Eligibility criteria specific to Key Question 2 (nonpharmacologic vs pharmacologic)

Intervention

- Nonpharmacologic intervention alone (no use of pharmacologic therapy)

Comparators

- Pharmacologic treatment alone

Dated: June 21, 2023

Marquita Cullom,

Associate Director.

[FR Doc. 2023-13581 Filed: 6/26/2023 8:45 am; Publication Date: 6/27/2023]